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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/992,680	11/19/2001	Chi-Huey Wong	84503	1046
24628	7590	02/13/2006	EXAMINER	
WELSH & KATZ, LTD 120 S RIVERSIDE PLAZA 22ND FLOOR CHICAGO, IL 60606			PRATS, FRANCISCO CHANDLER	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 02/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

09/992,680

Applicant(s)

WONG ET AL.

Examiner

Francisco C. Prats

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 23 November 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 21-26, 28, 29 and 52-57.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attachment.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____.
13. ☐ Other: _____.

Francisco C. Prats
Primary Examiner
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ATTACHMENT TO ADVISORY ACTION

The after-final response filed January 23, 2006, has been received and considered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

The information disclosure statement filed January 23, 2006, fails to comply with 37 CFR 1.97(d) because it lacks a statement as specified in 37 CFR 1.97(e).

The information disclosure statement filed January 23, 2006, also fails to comply with 37 CFR 1.97(d) because it lacks the fee set forth in 37 CFR 1.17(p). It has been placed in the application file, but the information referred to therein has not been considered.

All of applicant's argument has been fully considered but is not persuasive of error.

With respect to the assertion that the rejection of record has done nothing more than demonstrate the presence of the two claimed enzymes in a Sigma catalog having similar catalytic conditions, this is incorrect. On the current record the claims recite a composition comprising two enzymes. The cited prior art discloses that one of the enzymes, the glycosyltransferase, is suited to making desirable products. The cited prior art discloses that the second enzyme, the nucleoside-diphosphate

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forming enzyme, makes the substrate required for the first enzyme. The cited prior art further shows that these two enzymes function at the same physical conditions of pH and temperature. Thus, it is respectfully submitted that the holding of evidence is soundly based, and therefore required under the law.

With all due respect, it is not accurate to characterize the present rejection as "discounting evidence of a world-recognized expert" (response of January 23, 2006). Dr. Paulson's opinion is regarded very highly. The opinion evidence presented by Dr. Paulson has therefore been carefully scrutinized and assessed. For example, Dr. Paulson's expert assertion, that the enzymes function at "quite different" pH values (Declaration of Dr. James C. Paulson, item 13) has been demonstrated on the record as being inaccurate, based on the disclosures of the cited references. See, e.g., office action of November 21, 2005, pages 9 and 10.

Therefore, respectfully, Dr. Paulson's opinion as to whether the artisan of ordinary skill would have reasonably expected the two enzymes recited in claim 21 to have functioned together in a single milieu, is based solely on the fact that the two enzymes are located in two different cellular compartments. While the Lodish textbook cannot be considered

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under the rules for filing information disclosure statements (i.e. the PTO-SB/08A cannot be initialed), it is noted that the enzymes recited in claim 21 act in different compartments in the cell. However, other than the different cellular locations of the enzymes, applicant has presented no fact supporting the opinion that there would not have been a reasonable expectation of success when combining these enzymes.

As discussed at length previously on the record, one of ordinary skill in the art looking to whether these enzymes would have been expected to function together would have looked to the known facts, i.e. required temperature, pH, and other conditions regarding the enzymes. Significantly, applicant has failed to produce any non-opinion evidence suggesting that enzymes from different cellular compartments would not have been expected to have functioned together. Thus, applicant's argument regarding the issue of reasonable expectation is entirely based on an opinion which is not directly supported by a fact which would necessarily have been considered directly relevant by the artisan of ordinary skill.

As to whether Prieels discloses an active enzyme, contrary to applicant's argument, that fact is clear, as evidenced by the reference's disclosure of an active enzyme.

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As to the fact that the enzymes were not combined despite the knowledge of the enzymes for a considerable amount of time, as discussed previously, contentions that the reference patents are old are not impressive absent a showing that the art tried and failed to solve the same problem notwithstanding its presumed knowledge of the references. See *In re Wright*, 569 F.2d 1124, 193 USPQ 332 (CCPA 1977). No such showing has been made. Moreover, applicant's argument in this regard is essentially that the claimed subject matter cannot be considered obvious, because no one performed the claimed subject matter before applicant. Thus, applicant argues essentially that the claimed subject matter cannot be obvious, because it is not anticipated. Applicant in effect seeks to ignore 35 U.S.C. § 103(a), which explicitly states (emphasis added):

A patent may not be obtained ***though the invention is not identically disclosed or described as set forth in section 102 of this title***, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Because the prior art suggests the claimed subject matter, for the reasons of record, a holding of obviousness is required.

Applicant again argues that the claims do not require an APT regenerating system. However, as pointed out in the previous office action, the Demain patent (U.S. Pat. 4,178,210)

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demonstrates that the PEP/pyruvate kinase ATP regeneration system was known in the art to generate ATP in multi-enzyme synthesis processes. Thus, one of ordinary skill would have recognized that Demain's methodology was useful in generating starting material required in Schachter's process. Moreover, applicant's argument that ATP is not required is confusing since applicant uses PEP/pyruvate kinase in exactly the manner disclosed in the prior art. See, e.g., specification at page 13 (Scheme 1), where PEP/pyruvate kinase is used to generate ATP. Thus, applicant's argument that the claimed process does not "require" ATP is entirely at odds with the process as actually disclosed. That is, applicant argues that ATP is not required in their process, yet simultaneously discloses a methodology, and recites claim limitations, which are entirely at odds with applicant's own argument.

As to the asserted failure of the rejections of record to come to grips with the limitation requiring the diphosphofucose forming enzyme in a catalytic amount, it is respectfully pointed out that the enzyme is disclosed as having catalytic activity. The enzyme is therefore disclosed as being present in a catalytic amount. Moreover, one of ordinary skill using the enzyme to prepare the substrate for the fucosyltransferase would

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not have been motivated to have used the enzyme in any amount other than a catalytic amount.

In sum, as discussed above, at their broadest, the claims recite a composition comprising two enzymes. The cited prior art discloses that one of the enzymes, the glycosyltransferase, is suited to making desirable products. The cited prior art discloses that the second enzyme, the nucleoside-diphosphate forming enzyme, makes the substrate required for the first enzyme. The cited prior art further shows that these two enzymes function at the same physical conditions of pH and temperature. Again, it is very respectfully submitted that the holding of evidence is soundly based, and therefore required under the law.

No claims are allowed.

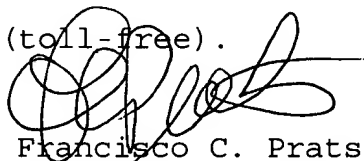
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C. Prats whose telephone number is 571-272-0921. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the

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organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Francisco C. Prats
Primary Examiner
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FCP